IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

BIOPLUS SPECIALTY PHARMACY SERVICES, INC.,))
Plaintiff,	Civil Action No. 1:18-cv-03370-WFK-ST
V.))) HIDV TRIAL DEMANDED
B.O.P. PHARMACY, INC.,) <u>JURY TRIAL DEMANDED</u>)
Defendant.	,)

DECLARATION OF ELVIN MONTANEZ

Pursuant to 28 U.S.C. § 1746, I, ELVIN MONTANEZ, declare under penalty of perjury as follows:

- I am over the age of eighteen and otherwise competent to make this declaration.
 Unless specifically indicated to the contrary, all statements in this declaration are based upon my personal knowledge.
- 2. I am the Chief Operating Officer of BioPlus Specialty Pharmacy Services, Inc. ("BioPlus"), the Plaintiff in the above-styled action.
- 3. This declaration is being offered in support of BioPlus' Motion for Preliminary Injunction to restrain Defendant B.O.P. Pharmacy, Inc. ("Defendant" or "B.O.P") from continuing its unauthorized infringement of BioPlus' registered "BIOPLUS" trademark.

BioPlus and its Business Model

4. BioPlus is a corporation organized and existing under the laws of the State of Florida and having its principal place of business located at 376 Northlake Boulevard, Altamonte Springs, Florida 32701. BioPlus is licensed to fill prescriptions in the State of New York.

- 5. BioPlus is one of the largest privately owned specialty pharmacies in the United States, and has been providing specialty pharmacy services, continuously to prescribers, doctors and patients nationwide since 1997.
- 6. Specialty pharmacies in general and BioPlus in particular are quite different from the storefront retail pharmacies most people are familiar with. As a specialty pharmacy, BioPlus provides prescription drugs for the treatment of a limited number of serious and chronic medical conditions or diseases with a focus on cancer, hepatitis C, multiple sclerosis, rheumatoid arthritis, and many other chronic diseases. Typically, the cost of these specialized drugs ranges from \$5,000 to \$30,000 per dispense. Generally, for cost and safety reasons, retail pharmacies do not inventory the specialized and expensive drugs required for the treatment of these conditions. BioPlus, on the other hand, routinely stocks a full inventory of the drugs used in the limited number of medical conditions and diseases it focuses on to ensure immediate and timely delivery to patients.
- 7. In addition, BioPlus provides services far beyond the mere fulfillment of a prescription. BioPlus works together with prescribers (typically physicians) and their patients on an individual basis to ensure optimal treatment. These services take a number of forms. At the outset, BioPlus offers an industry-leading 2-Hour Patient Acceptance Guarantee Program (the "Guarantee Program"). Through this Program, BioPlus guarantees notification to medical providers/patients in less than two (2) hours whether their patients can be qualified pending insurance verification or are not qualified and need to be sent to an alternate supplier. BioPlus' Guarantee Program reduces the wait time for patients and providers from days down to a mere two (2) hours, making BioPlus faster, on average, than its competitor specialty pharmacies. This quick turnaround in turn enhances the quality of care to patients and care engagement.

- 8. BioPlus also acts as the prescribing physicians' partner in effective management of serious illnesses through end-to-end education, monitoring, and analysis of the therapy process. For example, BioPlus provides detailed and patient advocacy and training, customized treatment programs specifically tailored to each patient, and compliance monitoring for all patients. BioPlus also offers information about therapies approaching FDA approval, study data, and education about best practices relevant to specialized therapies. BioPlus also offers nationwide free overnight delivery for its customers/patients, a particularly useful service that BioPlus' customers have come to rely on as a hallmark of BioPlus' customer service, particularly with respect to the expensive specialized drugs it ordinarily dispenses.
- 9. Finally, and uniquely in the specialty pharmacy industry, BioPlus proactively works with patients and pharmaceutical manufacturers to directly enroll patients in cost saving programs and discounts offered directly by the drug manufacturer (the "Collaborative Process"), often saving patients thousands of dollars each year through this unique Collaborative Process.
- 10. As a result of these value added services, over time BioPlus has developed strong relationships with prescribers and payors.

The Electronic Rx System

11. The electronic prescription system (eRx), is an integrated electronic framework that allows prescribing physicians and other medical practitioners to write and send prescriptions to a participating pharmacy electronically, instead of using handwritten or faxed notes or calling in prescriptions. This process utilizes an electronic framework that functions as an online directory of pharmacies, wherein physicians and nurse practitioners can search for and identify a pharmacy to service the needs of a particular patient, which ensures accuracy and enhances patient safety and quality of care by ensuring prescriptions are transmitted directly to the

pharmacy chosen by the physician prescriber, with the intent of eliminating risks associated with paper prescriptions and the use of third-parties. BioPlus is authorized to and receives eRx prescriptions from prescribers in all 50 states.

- 12. This eRx system is only effective, however, when a prescribing physician is able to properly identify and transmit its patient's prescription to the intended pharmacy free from error or confusion.
- 13. An important feature of the eRx system is the use of a clearinghouse or exchange that verifies both prescribers and pharmacies. These clearinghouse functions are performed by SureScripts. All eRx submissions are through SureScripts. This entity certifies the credentials of prescribers and pharmacies so that an eRx is not transmitted unless both the prescriber and pharmacy are qualified. Based on my personal experience, SureScripts does not communicate with pharmacies and hence will not involve itself in tradename disputes. As long as a pharmacy is vetted as having proper licensures, it is authorized to receive eRxes if a prescriber selects it in the electronic listing of pharmacies.
- 14. In recent years, many states across the country have begun requiring that all prescriptions be sent through the eRx system. For example, in New York State, the state in which Defendant B.O.P. operates, prescriptions are now required by law to be written and submitted to a pharmacy exclusively through the eRx system. Because of these laws, the use of the eRx system by prescribers, and reliance on the eRx system by pharmacies, has increased exponentially, making the eRx platform critically important to the overall success and business of a specialty pharmacy such as BioPlus.
- 15. New York State also restricts prescriptions to one refill. This legal requirement has the effect of causing prescribers to consult the electronic lists of pharmacies more frequently.

The BIOPLUS Mark

- 16. BioPlus is the owner of U.S. Trademark Registration No. 2,329,227 (the "227 Registration") for BIOPLUS (the "BIOPLUS Mark") for "[m]edical services, namely, chronic disease management consisting of therapy, medication and treatment". The '227 Registration was registered on March 14, 2000. A true and correct copy of the registration certificate for the BIOPLUS Mark is attached as **Exhibit A** to BioPlus' Motion for Preliminary Injunction.
- 17. The BIOPLUS Mark is incontestable. On February 8, 2006, BioPlus filed its affidavit of incontestability pursuant to 15 U.S.C. §1065 and it was accepted by the USPTO on April 5, 2006. A true and correct copy of the USPTO's Notice of Acceptance of the affidavit of incontestability is attached to the Motion for Preliminary Injunction as **Exhibit B**.
- 18. For over twenty (20) years, BioPlus has been using the BIOPLUS Mark to advertise and sell its prescription drugs and associated services, including through its website, located at www.bioplusrx.com, since at least 2006.
- 19. During this time, BioPlus has invested considerable resources to marketing its prescription drugs and services under the BIOPLUS Mark, which is featured prominently in its advertising and promotional materials for these services throughout the United States.
- 20. As a result of the foregoing, the BIOPLUS Mark is highly associated with BioPlus and BioPlus' specialty prescription drugs and services, particularly with respect to prescribers as well as payors such as pharmacy benefits managers and managed care providers and systems that treat or pay for the treatment of serious medical conditions and diseases like hepatitis C, cancer, multiple sclerosis, and rheumatoid arthritis.
- 21. Due to BioPlus' longtime, consistent, and exclusive use and promotion of its specialty medical and pharmacy services under the BIOPLUS Mark, prescribers, payors,

providers and their patients have come to know and recognize the BIOPLUS Mark as a designation identifying BioPlus as the source of high quality and specialized pharmaceutical products and services provided under this mark. Accordingly, the BIOPLUS Mark has developed and represents substantial goodwill and is an asset of substantial value to BioPlus, which value and goodwill rightfully belongs exclusively to BioPlus.

Defendant B.O.P. and It's Harm to BioPlus

- 22. As a result of an earlier incident, it is my understanding that since at least 2004 Defendant B.O.P. has operated a pharmacy in Flushing, New York, alternatively under the name(s) Bio Plus Pharmacy, Bio Plus Pharmacy, Inc., and/or Bio Plus Pharmacy, Inc. and Surgical Supplies.
- 23. It is my understanding that Defendant B.O.P. is a regionally based community pharmacy; it is not a specialty pharmacy and does not offer or provide any of the specialized drugs and associated services provided by BioPlus. It is my understanding that it is licensed to fill prescriptions only in the State of New York.
- 24. BioPlus first became aware of Defendant B.O.P.'s existence in 2011 after Walgreens mistakenly mailed a check for \$28,774.80, meant for BioPlus, to Defendant B.O.P. After the check was received and cashed by a representative for Defendant B.O.P., BioPlus advised B.O.P. of its incontestable trademark and B.O.P. assured BioPlus that it would change its name and cease using the name "BioPlus" in any manner in connection with the offering or sale of medical or pharmacy services.
- 25. Thereafter, on December 19, 2011, Defendant B.O.P. filed documents with the New York State Department of State to change its legal name to B.O.P. Pharmacy, Inc. and it is still registered in that name. A true and correct copy of the screenshot of the corporate

information for Defendant B.O.P. is attached to the Motion for Preliminary Injunction as **Exhibit**C. This page was last accessed via https://www.dos.ny.gov/corps/bus_entity_search.html on

June 28, 2018.

- 26. At a time unknown to BioPlus, B.O.P. resumed its use of the Bio Plus trade name and mark. Although it changed its name with the New York State Division of Corporations and New York Pharmacy Board, to my understanding Defendant B.O.P. is using "Bio Plus" as its trade name in all other material respects.
- 27. BioPlus confirmed that Defendant B.O.P. had resumed use of the BioPlus tradename and Mark in May, 2018. At that time, BioPlus was in negotiations with a large national managed care company headquartered on the West Coast. That company informed us that it uncovered this other pharmacy doing business as "Bio Plus" during its due diligence. Attached to the Motion for Preliminary Injunction as **Exhibit H** is a true and correct copy of the listing in the Caremark Rx Claim directory under the name "Bio Plus Pharmacy, Inc." that the managed care company provided to us.
- 28. I advised Amar Patel, Pharmacy Manager of BioPlus' retail pharmacy in Newburgh, New York, of this development.
- 29. About the same time, BioPlus' Regional Clinical Liaison in the New York City area personally visited B.O.P., and reconfirmed that B.O.P. was regularly receiving eRx prescriptions for specialty pharmaceuticals it could not fill.
- 30. Defendant B.O.P. continues to operate under the name Bio Plus Pharmacy Inc. with respect to the eRx system. On information and belief, Defendant B.O.P. also lists its business name as "Bio Plus Pharmacy Inc." with the National Council for Prescription Drug Program ("NCPDP"), which maintains a comprehensive online directory of pharmacies by which

prescribers (i.e., BioPlus' and Defendant's customers) can look to locate a pharmacy from which to request prescription filling services for their patients. Defendant B.O.P. also lists its name as "Bio Plus" in its SureScripts certification. A true and correct copy of a screenshot of SureScripts' electronic directory listing for B.O.P. is attached to BioPlus' Motion for Preliminary Injunction as **Exhibit I**. This page was last accessed on June 28, 2018. Notice that because B.O.P.'s listing is two words, BioPlus does not immediately follow B.O.P. and is not even on the same page of this SureScripts' screenshot. As a result, an unknown number of prescriptions have been diverted from BioPlus and an unknown number of prescription orders have been lost by BioPlus.

- 31. BioPlus relies significantly on the eRx system as the primary means by which it receives prescriptions from prescribers across the country. As a result of the virtually identical sound and appearance of the BIOPLUS Mark and Defendant B.O.P's infringing name, Plaintiff BioPlus has experienced many instances of actual confusion on the part of providers and payors who have misdirected prescription orders and at least one payment to Defendant B.O.P. These misdirected prescriptions, to the extent known, continue to cause significant economic harm to BioPlus in a manner that eludes full determination or calculation. BioPlus is not only unaware of the extent of misdirected prescriptions, but it is also difficult if not impossible to ascertain which prescribers or payors may be lost for future business because of BioPlus' perceived nonresponsiveness. And there is no way to determine any other potential customers who may be lost because of disappointed prescribers or payors giving negative or neutral recommendations after a bad experience resulting from a misdirected prescription.
- 32. Because Defendant B.O.P.'s infringing "Bio Plus" name appears alphabetically *above/before* BioPlus' name in the eRx system (note the space in B.O.P.'s infringing "Bio Plus"

name which places it ahead of "BioPlus" alphabetically), Defendant B.O.P. is presented to prescribers in the eRx system before BioPlus. Further, as previously noted, our BioPlus listing does not immediately follow B.O.P.'s. As a consequence of the extensive investment of time and resources to develop a package of services that is a part of our prescription offerings, prescribers expect instant responsiveness and significant interactions with BioPlus when they request us to fill their prescriptions. This intangible goodwill is insidiously undermined and impaired, to an unknown extent, when the real BioPlus does not respond at all to their orders. Moreover, even if misdirected eRx prescriptions are promptly forwarded to BioPlus, the time lag still impairs our ability to comply with our 2-hour Guarantee Program. BioPlus' business and reputation depends on its built-up relationships and goodwill established over time with physician prescribers and particularly its Guarantee Program.

- 33. In addition, BioPlus' ability to meet its obligations under its nationwide free overnight delivery for customers/patients, is severely compromised when a prescriber mistakenly and unknowingly transmits a prescription to Defendant that was intended for BioPlus. Aside from the erosion of goodwill from BioPlus that results when BioPlus is unable to meet these obligations, the prescriber's patient is at risk when the timelines of delivery of the specialized drug is critical. This consequence is exacerbated by the fact that specialized drugs are not routinely maintained in inventories of retail pharmacies and the supply sources are limited.
- 34. I also question whether B.O.P. is an entity that is intended and authorized to receive protected health information ("PHI") of the patients of misdirected eRxes, which are HIPAA violations.
- 35. The stopgap arrangement for forwarding misdirected prescriptions to BioPlus does not adequately protect BioPlus' trademark rights, associated business model and goodwill.

First, there is no way to ensure that misdirected prescriptions are forwarded timely or at all. As

described above, any time lag can impair BioPlus' ability to satisfy its 2-hour Guarantee

Program. Longer lags may adversely affect patient care in time sensitive cases. And there is no

effective way for monitoring this voluntary undertaking or to determine whether all misdirected

prescriptions have been transferred to us. The only way to end this obvious confusion is to

completely eliminate B.O.P.'s ability to use the trade name "BioPlus" and any similar or

derivative names.

I declare under penalty of perjury that the foregoing is true and correct to the best of my

knowledge.

Executed on this 2 day of July, 2018.

Elvin Montanez

Chief Operating Officer

BioPlus Specialty Pharmacy Services, Inc.